## REMARKS

This Amendment is responsive to the Final Office Action dated August 8, 2007. Applicant has amended claim 14 and added new claims 20-25. Claims 1-25 are pending.

**Preliminary Matter**

Applicant notes that it appears that the Examiner has not yet indicated his consideration of the Information Disclosure Statement filed with this application on November 1, 2003. Applicant respectfully requests that the Examiner indicate such consideration by returning the initialed 1449 form provided with the Information Disclosure Statement filed November 1, 2003 in the next action.

**Claim Rejection Under 35 U.S.C. § 103**

In the Final Office Action, the Examiner rejected claims 1-13 and 15-19 under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,338,345) in view of Goupil (US 6,652,883), and rejected claim 14 under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. in view of Durgin (US 6,591,838).

Applicant respectfully traverses the rejection. Applicant maintains that the applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

*Claims 1-5*

Independent claim 1 defines a method for treating urinary incontinence comprising applying vacuum pressure to an instrument proximate to a urethral wall to draw a portion of the urethral wall into a cavity in the instrument, forming a hole in the portion of the urethral wall disposed in the cavity, and implanting a bulking prosthesis through the hole proximate to a urethral sphincter.

In the Final Office Action, the Examiner cited Johnson as disclosing a device used to deliver a bulking prosthesis to the body. The Examiner acknowledged that Johnson describes the device for treating GERD, and fails to teach using the bulking prosthesis for treating urinary

incontinence. The Examiner pointed to Goupil, however, as teaching that it is well known to use a bulking material to treat a variety of problems including GERD and urinary incontinence. On this basis, the Examiner stated that modifying Johnson such that the bulking device is used to treat urinary incontinence would have been obvious in view of the Goupil device.

Applicant continues to disagree with the Examiner's obviousness rejection. Again, there would have been no apparent reason for one of ordinary skill in the art to modify Johnson to conform to the claimed invention. Johnson describes a particular delivery device and technique for controllably delivering a prosthetic bulking device to treat GERD. Goupil teaches a variety of compositions for tissue bulking and coating. However, there is no teaching in Goupil that would have suggested reducing the size of the Johnson device and adapting the device for application to urinary sphincter bulking. Goupil focuses on particular compositions for bulking articles, and describes no delivery devices or techniques similar to those of Johnson for urethral bulking.

Neither Goupil nor Johnson provides any teaching that would have suggested the application of vacuum pressure to an instrument proximate to a urethral wall to draw a portion of the urethral wall into a cavity in the instrument, as set forth in claim 1. Although vacuum pressure is described by Johnson in the context of esophageal bulking for GERD, neither Johnson nor Goupil contemplates the substantial miniaturization that would have been required to render such a device suitable for use in the much smaller lumen afforded by the urethra. Nor do Johnson and Goupil provide any teaching that would have suggested a reasonable expectation of success for application of vacuum pressure to deliver bulking materials in the urethra.

The Examiner stated that "Goupil discloses that is well known to use a bulking material to treat both GERD and urinary incontinence." In Goupil, there is no suggestion of the desirability or suitability of applying vacuum pressure to a urethral wall to deliver a bulking material. Also, as acknowledged by the Examiner, Johnson does not contemplate bulking of the urethral wall. Therefore, one of ordinary skill in the art would have found no teaching in Johnson and Goupil that would have suggested modification of the technique described by Johnson to deliver bulking prostheses proximate to the urethral sphincter, as claimed. The desirability of such a modification would have been apparent only upon access to Applicant's disclosure, which is impermissible.

Goupil merely describes the use of a catheter, syringe or spray device for delivery of bulking materials.[1] However, Goupil indicates that "a multi-lumen catheter is used to deliver the composition to the intended site of administration."[2] In particular, for compositions including different components, the delivery methods and devices described by Goupil require a multi-lumen catheter to deliver the compositions at the delivery site. Goupil describes preformed bulking and sealing articles[3], but appears to provide no mention of techniques for delivery of a preformed article other than by catheter.[4]

In Johnson and Goupil, there is no teaching that would have suggested adaptation of the particular delivery technique described by Johnson for esophageal bulking to support urethral bulking, notwithstanding the Examiner's statement that bulking can be used for GERD or urinary incontinence. In other words, even if bulking was generally desirable for GERD and urinary incontinence, one of ordinary skill in the art still would not have appreciated the desirability of modifying and adapting the specific technique described by Johnson for esophageal bulking so that it could be used for urethral bulking, particularly given substantial differences in tissue sizes and characteristics.

Dependent claims 2-5 are allowable for at least the reasons put forth with respect to independent claim 1, from which they depend.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 1-5 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

***Claims 6-9***

Independent claim 6 recites a system that includes a tubular instrument sized for introduction into a urethra, the distal end including a cavity. Claim 6 also requires a vacuum port to draw a portion of a urethral wall into the cavity, a needle to make a hole through the urethral wall in the portion of the urethral wall disposed in the cavity, and a pushing agent to push a

[1] Goupil, Col. 16, ll 40-43.
[2] Goupil et al., Col. 16, ll. 43-44.
[3] Goupil et al., Col. 13, ll. 36-43.
[4] Goupil et al., Col. 16, ll. 30-37 and 40-43.

bulking prosthesis through the tubular instrument and through the hole in the urethral wall. Johnson in view of Goupil fails to teach or suggest the elements of independent claim 6.

Neither Johnson nor Goupil provides any teaching that would have suggested miniaturization of the Johnson device to include a tubular instrument sized for introduction into a urethra, as claimed. Johnson discloses a delivery device that delivers a "bulking device below a tissue surface such as below the mucosa to treat gastroesophageal reflux disease."[5] As mentioned in the previous response, Johnson teaches that cap 50 of FIG. 16 has "an outside diameter of about 0.6 inches"[6] and that the "outside diameter of the overtube [of FIG. 17] is about 0.7 inches."[7] The dimensions of the Johnson device are far too large to be introduced into a urethra, and Johnson does not describe the use of the device within a urethra.

Johnson does not describe the delivery of bulking devices anywhere other than in the esophagus of a patient. In addition, there is no suggestion of modifying the scale of the Johnson device in order to allow the Johnson device to be introduced into a urethra. Goupil merely recognizes that bulking may be useful for GERD or urinary incontinence. The Goupil reference provides no suggestion of the adaptation and substantial miniaturization of the particular device described by Johnson for use in the urethra.

Dependent claims 7-9 are allowable for at least the reasons put forth with respect to independent claim 6, from which they depend. Johnson fails to disclose each and every limitation set forth in claims 6-9, as amended. For at least these reasons, the Johnson reference would not support a prima facie case of anticipation of Applicant's claims 6-9 under 35 U.S.C. 102(b). Withdrawal of this rejection is requested.

***Claims 10-13 and 15***

Independent claim 10 defines a device comprising a bulking prosthesis in the shape of a partial cylinder having an inner radius, wherein the bulking prosthesis comprises a hydrophilic polymer that forms a hydrogel in the presence of water. Claim 10 also requires that the inner radius of the partial cylinder is sized to conform to close the urethra of a patient when the bulking prosthesis is implanted in the patient with an inner surface coaxial with the urethra of the patient

[5] Johnson et al., Abstract.
[6] Johnson et al., Col. 11, ll. 62-63.
[7] Johnson et al., Col. 13, ll. 60-61.

and when the patient exercises voluntary control over an external urethral sphincter. Johnson and Goupil fails to teach or suggest the elements of independent claim 10.

In the Office Action, the Examiner stated that Johnson teaches that the bulking prosthesis can take on a wide variety of shapes and sizes and that these optimal dimensions are patient specific and can be determined through routine experimentation of one skilled in the art. Yet, the Examiner did not identify any teaching within Johnson that would have suggested the use of a bulking prosthesis in the shape of a partial cylinder. Hence, a partial cylinder shape is not among the "wide variety of shapes and sizes" contemplated by Johnson. Goupil provides no teaching sufficient to overcome this deficiency in Johnson.

The Examiner stated that "[s]ince it is known to use a variety of shapes this is considered to include a partial cylinder depending on the shape that is best for the intended use of the device." However, whether it contemplates a variety of shapes or not, the Johnson reference provides no teaching concerning the specific shape required by the claims. Nor does Johnson mention how a partial cylinder or other shape would have been desirable for a particular intended use, particularly inasmuch as Johnson does not even contemplate any use within the urethra.

The Johnson reference, taken alone or in combination with Goupil, provides no apparent reason why one of ordinary skill in the art would select a partial cylinder shape for a bulking prosthesis. Clearly, one of ordinary skill in the art would not have found any suggestion in Johnson or Goupil of a partial cylinder bulking prosthesis having an inner radius that is sized to conform to close the urethra when the patient exercises voluntary control over an external urethral sphincter. These shape and dimension limitations in claim 10 are structural requirements and not a matter of mere intended use.

Johnson describes an esophageal bulking device 16 comprising "an oblong, cylindrical, elliptical, toric or pillow shape."[8] In addition, FIGS. 3, 4, 5 and 6 show bulking devices with generally circular or oval cross-sectional configurations. However, Johnson does not contemplate any bulking prosthesis in the shape of a partial cylinder having an inner radius, as defined in claim 10. Johnson also fails to provide any suggestion of a similar shape or a device configured to deploy such a bulking prosthesis.

[8] Johnson et al., Col. 6, ll. 50-52.

In addition to lacking a suggestion of a partial cylinder shape, Johnson does not teach or suggest a bulking prosthesis having an inner radius of such a partial cylinder that is sized to conform to close the urethra of a patient. Johnson describes bulking devices in which "a larger transverse cross-sectional area will produce a higher closing pressure."[9] Given Johnson's focus on GERD, there would have been no reason for one of ordinary skill in the art to consider a bulking prosthesis having an inner radius of the partial cylinder that is sized to conform to close the urethra of a patient. Goupil adds nothing concerning the desirability of such a shape.

Dependent claims 11-13 and 15 are allowable for at least the reasons put forth with respect to independent claim 10, from which they depend.

Johnson fails to disclose each and every limitation set forth in claims 10-13 and 15. For at least these reasons, Johnson does not support a prima facie case of anticipation of Applicant's claims 6-9 under 35 U.S.C. 102(b). Withdrawal of this rejection is requested.

*Claims 16-19*

Independent claim 16, as amended, requires a method for treating urinary incontinence comprising applying vacuum pressure to tissue proximate the urethral sphincter, and implanting a bulking prosthesis in the portion of the tissue proximate to the urethral sphincter. The bulking prosthesis is in a miniature state at the time of implantation and assumes an enlarged state after implantation, and the bulking prosthesis includes a long dimension of at least two millimeters in the enlarged state.

For substantially the reasons stated above with respect to claim 1-5, it would not have been obvious to modify the delivery techniques described by Johnson to implant a bulking prosthesis in tissue proximate a urethral sphincter to treat urinary incontinence. Again, there would have been no apparent reason, whether discerned from Johnson, Goupil, or any other reference, to modify a device designed for use in the esophagus to deliver bulking agents for bulking of the urethral sphincter.

Dependent claims 17-19 are allowable for at least the reasons put forth with respect to independent claim 16, from which they depend. For at least these reasons, the prior art

[9] Johnson et al., Col. 6, ll. 45-47.

references fail to support a prima facie case for unpatentability of Applicant's claims 16-19 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

***Claim 14***

Dependent claim 14 is allowable for at least the reasons put forth with respect to independent claim 10, from which it depends. Durgin provides no teaching sufficient to overcome the basic deficiencies evident in the Johnson reference.

**New Claims:**

Applicant has added claims 20-25 to the pending application. No new matter has been added by the new claims.

The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions.

With respect to claim 20, for example, the Johnson and Goupil references would not have suggested the method of claim 16, wherein the bulking prosthesis comprises a first bulking prosthesis and a second bulking prosthesis, each of the first and second bulking prostheses comprising a partial cylinder bulking prosthesis, and wherein implanting a bulking prosthesis comprises implanting the first and second bulking prostheses in portions of the tissue proximate to the urethral sphincter on opposite sides of a urethra of the patient.

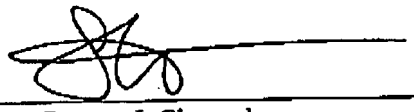
With respect to claim 21, the applied references also fail to disclose or suggest partial cylinder bulking prostheses having an inner surface radius that is sized to conform to close the urethra of the patient when the patient exercises voluntary control over an external urethral sphincter.

With respect to claims 22-24, the applied references provide not teaching that would have suggested a bulking prosthesis shaped as a partial cylinder having a substantially C-shaped cross section.

## CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 12-10-07

By: 

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